Cullinan Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full Year 2024 Financial Results

February 27, 2025

Initial clinical data from global Phase 1 study of CLN-978 in Systemic Lupus Erythematosus (SLE) expected in Q4 2025; CLN-978 remains the first and only development-stage CD19 T cell engager in an autoimmune disease clinical trial in the U.S.

Zipalertinib pivotal Phase 2b study met primary endpoint; full results mid-year 2025 and NDA submission planned H2 2025, pending regulatory discussions

Cash and investments of $606.9 million as of December 31, 2024, continues to provide runway into 2028

CAMBRIDGE, Mass., Feb. 27, 2025 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM; "Cullinan"), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today reported recent and anticipated business highlights and announced its financial results for the fourth quarter and full year ended December 31, 2024.

"Building on our execution throughout 2024, we are positioned to again deliver meaningful catalysts in 2025, starting with key updates for CLN-978 and zipalertinib," said Nadim Ahmed, Chief Executive Officer of Cullinan Therapeutics. "We have established an important competitive advantage in the immunology space as CLN-978 remains the first and only development-stage CD19 T cell engager with U.S. Food and Drug Administration (FDA) IND clearance in autoimmune diseases. We are further strengthening our leadership position by rapidly expanding our site footprint and preparing to deliver initial clinical data in SLE in the fourth quarter of 2025. For zipalertinib, we recently announced that the pivotal Phase 2b portion of the REZILIENT1 study met the primary endpoint of overall response rate. This milestone marks a significant achievement for Cullinan, our partner, Taiho, and most importantly, patients with EGFR exon20 insertion mutation NSCLC who have received prior therapy. Together with Taiho, we look forward to discussing next steps with the U.S. FDA and expect to submit an NDA in the second half of 2025. We look forward to continuing to progress these programs along with the rest of our pipeline."

Portfolio Highlights

Immunology

- **CLN-978 (CD19xCD3 T cell engager):** Systemic lupus erythematosus and rheumatoid arthritis
    - The global Phase 1 study in moderate to severe SLE is ongoing with site expansion in the United States, Europe and Australia, and the Company plans to share initial clinical data in the fourth quarter of 2025.
    - The Company remains on track to initiate a Phase 1 study in rheumatoid arthritis (RA) in the second quarter of 2025. The company-sponsored trial will be designed and executed in collaboration with FAU Erlangen-Nuremberg in Germany and Università Cattolica del Sacro Cuore, Rome in Italy.

Oncology

- **CLN-619 (Anti-MICA/MICB monoclonal antibody)**: Solid tumors and hematological malignancies
    - The Company continues enrollment of disease-specific expansion cohorts of its Phase 1 study. Cullinan remains on track to report initial data for endometrial and cervical cancers in the second quarter of 2025.
    - Enrollment continues in the ongoing Phase 1 study of CLN-619 in patients with relapsed/refractory multiple myeloma.
- **Zipalertinib (EGFR ex20ins inhibitor), collaboration with Taiho Oncology:** EGFR ex20ins NSCLC
    - In January 2025, Cullinan announced that the pivotal Phase 2b portion of REZILIENT1 met the primary endpoint of overall response rate in patients with EGFR ex20ins NSCLC who have received prior therapy. The full results will be submitted for presentation at an upcoming international medical conference and shared mid-year 2025. Pending discussions with the U.S. FDA, Taiho and Cullinan plan to submit for U.S. regulatory approval in the second half of 2025. Taiho continues enrollment of the pivotal study REZILIENT3 in 1L EGFR ex20ins NSCLC.

- **CLN-049 (FLT3xCD3 T cell-engaging bispecific antibody):** AML and MDS
  - Enrollment continues in the ongoing Phase 1 study in patients with relapsed/refractory AML or MDS, and in the ongoing Phase 1 study in patients with measurable residual disease (MRD) in AML.

- **CLN-617 (IL-2 and IL-12 cytokine fusion protein):** Solid tumors
  - Enrollment continues in the ongoing Phase 1 study in patients with advanced solid tumors.

Fourth Quarter and Full Year 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, short- and long-term investments, and interest receivable were $606.9 million as of December 31, 2024. Cullinan continues to expect its cash resources to provide runway into 2028 based on its current operating plan.
- **R&D Expenses:** Research and development expenses were $40.5 million for the fourth quarter of 2024, compared to $34.8 million for the same period in 2023, and $142.9 million for the full year 2024, compared to $148.2 million for the full year 2023.
- **G&A Expenses:** General and administrative expenses were $14.6 million for the fourth quarter of 2024, compared to $10.6 million for the same period in 2023, and $54.0 million for the full year 2024, compared to $42.5 million for the full year 2023.
- **Net Loss:** Net loss attributable to Cullinan was $47.6 million for the fourth quarter of 2024, compared to $23.8 million for the same period in 2023, and $167.4 million for the full year 2024, compared to $153.2 million for the full year 2023.

About Cullinan Therapeutics

Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients. Cullinan has strategically built a diversified portfolio of clinical-stage assets that inhibit key drivers of disease or harness the immune system to eliminate diseased cells in both autoimmune diseases and cancer. Cullinan's portfolio encompasses a wide range of modalities, each with the potential to be best and/or first in class. Anchored in a deep understanding of oncology, immunology, and translational medicine, we create differentiated ideas, identify the most appropriate targets, and select the optimal modality to develop transformative therapeutics across a wide variety of autoimmune and cancer indications. We push conventional boundaries from candidate selection to differentiated therapeutic, applying rigorous go/no go criteria at each stage of development to fast-track only the most promising molecules to the clinic and, ultimately, commercialization. With deep scientific expertise, our teams exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients. Learn more about Cullinan at https://cullinantherapeutics.com/, and follow us on LinkedIn and X.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding the company's beliefs and expectations regarding: our preclinical and clinical developments plans and timelines for our product candidates, the clinical and therapeutic potential of our product candidates, the strategy of our product candidates, our research and development activities, our plans regarding future data presentations, our cash runway, and other statements that are not historical facts. The words "believe," "continue," "could," "estimate," "expect," "intends," "may," "plan," "potential," "project," "pursue," "will," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events and are subject to known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: uncertainty regarding the timing and results of regulatory submissions; the risk that any INDs or other global regulatory submissions we may file with the United States Food and Drug Administration or other global regulatory agencies are not cleared on our expected timelines, or at all; the success of our clinical trials and preclinical studies; the risks related to our ability to protect and maintain our intellectual property position; the risks related to manufacturing, supply, and distribution of our product candidates; the risk that any one or more of our product candidates, including those that are co-developed, will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; and the success of any collaboration, partnership, license or similar agreements. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, including under the caption "Risk Factors" in our most recent Annual Report on Form 10-K and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change, except to the extent required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release. Moreover, except as required by law, neither the company nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made.

Cullinan Therapeutics, Inc.
Selected Condensed Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	December 31, 2024	December 31, 2023
Cash, cash equivalents, investments, and interest receivable	$ 606,917	$ 468,264
Total assets	$ 621,824	$ 484,182
Total current liabilities	$ 30,647	$ 28,137
Total liabilities	$ 31,496	$ 30,287
Total stockholders' equity	$ 590,328	$ 453,895

Cullinan Therapeutics, Inc.
Consolidated Statements of Operations
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended		Twelve Months Ended	
	December 31, 2024	December 31, 2023	December 31, 2024	December 31, 2023
Operating expenses:				
Research and development	$ 40,492	$ 34,848	$ 142,903	$ 148,156
General and administrative	14,556	10,637	54,016	42,493
Total operating expenses	55,048	45,485	196,919	190,649
Impairment of long-lived assets	—	—	-	(440)
Loss from operations	(55,048)	(45,485)	(196,919)	(191,089)
Other income (expense):				
Interest income	7,512	5,917	29,660	21,627
Other income (expense), net	6	(117)	(199)	239
Net loss before income taxes	(47,530)	(39,685)	(167,458)	(169,223)
Income tax expense (benefit)	117	(14,122)	117	(14,122)
Net loss	(47,647)	(25,563)	(167,575)	(155,101)
Net loss attributable to noncontrolling interests	—	(1,760)	(192)	(1,939)
Net loss attributable to Cullinan	$ (47,647)	$ (23,803)	$ (167,383)	$ (153,162)
Basic and diluted net loss per share attributable to Cullinan:				
Common stock	$ (0.73)	$ (0.48)	$ (2.78)	$ (3.21)
Preferred stock	$ (7.32)	$ (4.83)	$ (27.78)	$ (32.12)
Weighted-average shares used in computing net loss per share attributable to Cullinan:				
Common stock	58,580	42,794	53,771	41,550
Preferred stock	648	648	648	614

Contacts:

Investors
Nick Smith
+1 401.241.3516
nsmith@cullinantx.com

Media
Rose Weldon
+1 215.801.7644
rweldon@cullinantx.com